UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/120,030	07/21/1998	BETH P GOLDSTEIN	7732-022-27	1743

7590 02/20/2004

PIPER RUDNICK, LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036-2412

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/120,030	GOLDSTEIN ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5,28,32,35,41-51,56-59 and 61-66* is/are pending in the application.

4a) Of the above claim(s) *28 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,32,41-51,56-59 and 61-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2003 has been entered.

Status of Claims

2. Pursuant to amendment filed 10/20/2003 claims 4, 5 are amended. Claims 61-66 are added. Claims 4,5, 28,32,35,41-51,56-59,61-66 are pending. Claims 28,35 remain withdrawn from consideration as being drawn to a non-elected groups. Applicant informed that claims 28, 35 would be canceled upon indication of allowable subject matter.

Claim Rejections - 35 USC § 112, first paragraph.

3. Claims 61,62,63,64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims introduce new matter not supported by specification as filed. Applicant directs to pages 8, 21-22; however said pages either address general information (p. 8) or discuss data related to treatment in rabbits (p. 20-21) whereas the instant claims are drawn to treatment of humans.

Claim Rejections - 35 USC § 103

4. Claims 4,5,32,41-51,56-59,61-66 remain rejected under 35 U.S.C. 103(a) as obvious over Zygmunt, and Goldberg and Stark, and further in view of Oldham. The rejection is maintained for the reasons of record as applied to claims 4,5,32,41-60, and further in view of the following.

In regard to Goldberg reference, applicant argues that the dosage effective in dogs was outside of the dosage range as instantly claimed. In particular, applicant points out that compared to the top limit of 30mg/kg/day in humans, the dosage described by Goldberg in dogs is as high as 31.6 or 35.4 mg/kg/day for dogs 5 and

4, respectively, that demonstrated full improvement. The dosages of less than 30mg/kg/day were initially effective but then was followed by relapse.

Examiner disagrees for several reasons. First, there is only a marginal difference between dosages described as effective on dogs in Goldberg and dosage range as instantly claimed. Compare, for example 31.6 or 35.4 mg/kg/day for dogs 5 and 4, respectively, with 30 mg/kg/day as claimed. The dosage is in the same order, and it would be *prima facie* to an artisan that dosage demonstrated to be effective in dogs should be fine-tuned for use in humans. Absent some teaching to the contrary (which is not offered by applicant), determination of particular ranges employed is within the skill of the ordinary worker as a part of the process of normal optimization. Second, as the instant claims are drawn to recombinant lysostaphin, and Oldham demonstrated that recombinant lysostaphin has antimicrobial activity similar to the natural product, it would be obvious, again, that the dosage of recombinant lysostaphin would be in the same range as for natural lysostaphin, but must be fine-tuned. Third, it is well known that actual activity of antibiotics is batch-dependent - this is why activity of antibiotics is often expressed in units of activity, rather[1] than in absolute units like mg/kg/day as in the instant claims - and, again, it would be obvious that determination of particular ranges of recombinant lysostaphin for use in

---

[1]See, for example Schuhardt et al. J. Bacteriol., vol. 88, 1964, p. 815, lines 4-8.

humans would be within the skill of the ordinary worker as a part of the process of normal optimization. Finally, instant specification itself supports the obviousness to determine a particular dosage range as it states that "suitable dosages and regiments of lysostaphin may vary with the severity of infection and the sensitivity of the infecting organism" (see p. 10, lines 5-9).

In regard to the use of combined therapy, see discussion of the Zygmunt reference.

5. Claims 32,42,43,46,47,50,51,54,55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zygmunt, and Goldberg and Stark, and Oldham as applied above, and further in view of Dixon. The rejection is maintained for the reasons of record.

Conclusion.

6. No claims are allowed

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is

(571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

February 13, 2004

mlb